4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-6730]

Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Device Reporting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection associated with requirements for medical device reporting for user facilities, manufacturers, importers, and distributors of medical devices.

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand

delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2017-N-6730 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Device Reporting." Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the

prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Medical Device Reporting--21 CFR Part 803

OMB Control Number 0910-0437--Extension

This information collection supports FDA regulations and FDA's Medical Device Reporting program. Section 519(a), (b), and (c) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360i(a), (b), and (c)) requires user facilities, manufacturers, importers, and distributors of medical devices to report adverse events involving medical devices to FDA. These provisions are codified in part 803 (21 CFR part 803), Medical Device Reporting. As amended most recently by the FDA Reauthorization Act of 2017 (FDARA) (Pub. L. 115-52) , medical device manufacturers and importers must submit medical device reports (MDRs) using FDA's electronic submission system. User facilities, however, may elect to submit reports using paper-based Form FDA 3500A--MedWatch--Mandatory Reporting (approved under OMB control number 0910-0291). The regulations also establish recordkeeping requirements and provide for certain exemptions, variances, or alternative forms of reporting. Exemptions and/or variances from individual reporting must be requested in writing and must receive Agency approval. Additionally, the regulations permit user facilities to submit paper-based annual reports, for which we have developed Form FDA 3419 entitled "Medical Device Reporting Annual User Facility Report."

This information collection also includes the use of existing formats such as Form FDA 3500A[1]--MedWatch--Mandatory Reporting to allow manufacturers to summarize in a single report multiple events with shared characteristics for device associated reportable malfunction events. For example, the Voluntary Malfunction Summary Reporting Program (VMSRP)[2] provides recommendations for manufacturers of certain devices to submit a single report that summarizes multiple device associated reportable malfunction events on a quarterly basis. The VMSRP was established under section 519(a)(1)(B)(ii) of the FD&C Act and reflects goals for streamlining malfunction reporting as outlined in the Medical Device User Fee Amendments (MDUFA) IV "Commitment Letter" for 2018 through 2022 agreed to by FDA and industry and

[1] Form FDA 3500A is approved under OMB control number 0910-0291.
[2] In the *Federal Register* of August 17, 2018 (83 FR 40973), FDA issued a notification permitting manufacturers to report certain device malfunction MDRs in summary form on a quarterly basis.

submitted to Congress. The Commitment Letter was finalized with the passage of FDARA on August 18, 2017, and, as passed, is entitled "MDUFA Performance Goals And Procedures, Fiscal Years 2018 Through 2022."[3]

The information that is obtained from this information collection will be used to evaluate risks associated with medical devices and enable FDA to take appropriate measures to protect the public health. Complete, accurate, and timely adverse event information is necessary for the identification of emerging device problems so the Agency can protect the public health under section 519 of the FD&C Act. FDA makes the releasable information available to the public for downloading on its website. Respondents are manufacturers and importers of medical devices and device user facilities.[4]

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden[1]

Activity/21 CFR Section	FDA Form No.	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours[2]
Exemptions/Variances--803.19		85	4	340	1	340
User Facility Reporting--803.30 and 803.32		520	10.06	5,232	0.35 (21 minutes)	1,831
User Facility Annual Reporting--803.33	3419	159	1	159	1	159
Importer Reporting, Death and Serious Injury--803.40 and 803.42		578	1	578	1	578
Manufacturer Reporting--803.50, 803.52 and 803.53		1,240	272.50	337,900	0.10 (6 minutes)	33,790
Voluntary Malfunction Summary Reporting Program		1,240	54.47	67,546	0.10 (6 minutes)	6,755
Supplemental Reports--803.56		1,050	128.71	135,148	0.10 (6 minutes)	13,515
Total						56,968

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Number has been rounded.

The number of respondents to the information collection is based on MDRs received by FDA recently. The annual frequency per response and total annual responses shown are based on the number of MDRs reported during the same period. FDA estimates that approximately 10

[3] Available at: https://www.fda.gov/downloads/ForIndustry/UserFees/MedicalDeviceUserFee/UCM535548.pdf.
[4] Device user facility means a hospital, ambulatory surgical facility, nursing home, outpatient diagnostic facility, or outpatient treatment facility as defined in § 803.3, which is not a physician's office (also defined in § 803.3).

percent of malfunction reports are submitted. Approximately 67 percent of the manufacturer reports received under 21 CFR 803.50, 803.52, and 803.53 are malfunction reports.

Supplemental Reports--21 CFR 803.56. We estimate that, at most, the number of supplemental reports is approximately one third of the total number of individual reports and summary reports submitted annually. Therefore, our estimate of the number of responses per respondent is 128.71.

Voluntary Malfunction Summary Reporting Program. The VMSRP includes the same respondent pool as individual manufacturer reporting. We expect that a summary report will take approximately the same amount of time to prepare as an individual report. (Note: device-led combination products are included in the burden estimate for the VMSRP.) As discussed in section I of the proposed VMSRP, FDA's Pilot Program for Medical Device Reporting on Malfunctions showed an 87 percent reduction in the volume of reporting for malfunction reports with use of malfunction summary reporting. Assuming 90 percent of malfunction reports are submitted in summary reports, we estimate that manufacturers would submit an average of 54.47 summary reports annually under the program.

Table 2.--Estimated Annual Recordkeeping Burden[1]

Activity/21 CFR Section	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
MDR Procedures--803.17	1,240	1	1,240	3.3	4,092
MDR Files--803.18	1,240	1	1,240	1.5	1,860
Total					5,952

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The number of respondents in table 2 is based on the MDRs reported to FDA's internal databases recently. We believe that the majority of respondents (manufacturers, user facilities, and importers) have already established written procedures and MDR files to document complaints and information to meet the MDR requirements as part of their internal quality control system. We have therefore adjusted our estimate downward.

Table 3.--Estimated Annual Third-Party Disclosure Burden[1]

Activity/21 CFR Section	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours[2]
Importer Reporting, Death and Serious Injury--803.40 and 803.42	578	25	14,450	0.35 (21 minutes)	5,058

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Number has been rounded.

The number of respondents for each CFR section in table 3 was identified from the MDRs reported to FDA's internal databases during the period recently.

Based on a review of the information collection since our last request for OMB approval, we have made no changes to our burden estimate.

Dated: April 21, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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